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IN THE

# Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,

*Petitioners,*

v.

APOTEX CORPORATION, APOTEX, INC. AND TORPHARM, INC.,

*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Whether the Federal Circuit erred in holding, in conflict with this Court's decision in *Tilghman* v. *Proctor*, 102 U.S. 707 (1881), and its progeny, that the "unwitting" and "unappreciated" prior creation of a product renders a subsequent patent of that product invalid as "inherently anticipated," and thus not novel under Section 102 of the Patent Act.

## PARTIES TO THE PROCEEDING

All parties to the proceeding are identified in the caption.

## RULE 29.6 STATEMENT

None of the parties has a parent corporation that is not listed as a party. No publicly held company owns 10% or more of the corporate party's stock.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners GlaxoSmithKline PLC, SmithKline Beecham Corporation d/b/a GlaxoSmithKline Inc., SmithKline Beecham PC and Beecham Group, PLC (collectively, "SmithKline Beecham") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

## OPINIONS BELOW

The opinion of the court of appeals is reported at 403 F.3d 1331 and included in the Appendix at 1a-55a. The initial panel opinion of the Federal Circuit, which was vacated by the *en banc* Federal Circuit, is included in the Appendix at 60a-108a. The opinions of the Federal Circuit concerning the court's granting in part of the petition for rehearing *en banc* are reported at 403 F.3d 1328 and included in the Appendix at 56a-60a. The opinions of the Untied States District Court for the Northern District of Illinois are reported at 286 F. Supp. 2d 925 (N.D. Ill. 2001), and 247 F. Supp. 2d 1011 (N.D. Ill. 2003), and included in the Appendix at 189a-219a and 109a-182a.

## JURISDICTION

The judgment of the Federal Circuit was entered on April 8, 2005, and the petition for rehearing *en banc* was denied on June 15, 2005. App. 220a-221a. The jurisdiction of the court of appeals was based on 28 U.S.C. § 1295(a)(1). On August 26, 2005, Chief Justice Rehnquist granted petitioners' motion to extend the time for filing of a petition for certiorari until October 13, 2005. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS

In pertinent part, 35 U.S.C. §§ 101 and 102 provide as follows:

> § 101. Inventions patentable
>
> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> * * * *
>
> § 102. Conditions for patentability; novelty and loss of right to patent
>
> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . .

## INTRODUCTION AND SUMMARY

In this case, the Federal Circuit radically expanded an important doctrine of patent law – the doctrine of inherent anticipation – by directly contravening the limits placed on that doctrine by this Court's established precedent concerning "accidental" or "unwitting" anticipation. Unless corrected, the Federal Circuit's newly-minted, unfettered doctrine of inherent anticipation will have profoundly harmful

consequences for innovation in the chemical, medical, biological and manufacturing arts.

This Court's decisions delineating the scope of inherent anticipation struck a careful balance between guaranteeing public access to the fruits of discovery and preserving the incentives necessary to encourage innovation. The Court's inherent anticipation cases bar patents for inventions or discoveries that were "anticipated" (even if only implicitly) in the prior art (*e.g.*, in prior patents and publications). But, in order to encourage discovery and invention, this Court's cases created a boundary making clear that if, unbeknownst to anyone, the practice of the prior art results in the production of a substance, then that prior art does *not* preclude a patent for the later discovery of the substance or the process of its production. The earlier production is instead an "unwitting" or "unappreciated" prior use that is patentable. See *Tilghman* v. *Proctor*, 102 U.S. 707 (1881); *Eibel Process Co.* v. *Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923).

In recent decisions, however, the Federal Circuit has destroyed this boundary and the balance crafted by this Court. The Federal Circuit now holds that a prior patent describing a compound and a process for making it inherently anticipates a later-issued patent claim to a different chemical compound, even though no one of ordinary skill in the art at the time of filing would have recognized or appreciated that the prior patent produced the later-claimed compound.

This case exemplifies the Federal Circuit's new rule. Specifically, the court invalidated SmithKline Beecham's patent claim covering paroxetine hydrochloride ("PHC") hemihydrate, the active ingredient in the antidepressant Paxil®, on the ground that the claim was "invalid for inherent anticipation," and thus not "novel" within the meaning of section 102 of the Patent Act. The court concluded that the claim had been anticipated by a prior patent on a *different substance*, even though no person had recognized that the practice of the prior patent results in PHC hemihydrate as a

byproduct. That holding flatly contradicts this Court's determination that "it would be absurd" to invalidate a patent on the ground that earlier inventors had "accidentally and unwittingly produced" the subject matter of the later patent. *Tilghman*, 102 U.S. at 711, 712. "[A]ccidental results, not intended and not appreciated, do not constitute anticipation" and thus do not preclude patent protection. *Eibel Process*, 261 U.S. at 66. By ruling that "anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created," App. 18a, the Federal Circuit ignored the established boundary of inherent anticipation and swept aside this Court's jurisprudence of accidental or unwitting prior use.

Dissenting emphatically below, Judge Newman explained:

> The panel now holds that a product that existed in trace amounts, although unknown and undetected and unisolated, is "inherently anticipated" and barred from the patent system after it is discovered. *The patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products [will] be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial components of existing materials.* [App. 59a (Newman, J., dissenting from denial of rehearing *en banc*) (emphasis supplied).]

The cost of discovering and developing new products such as pioneer drugs may run into the hundreds of millions of dollars – an investment of resources and time that cannot be justified if the resulting product can be rendered unpatentable by a subsequent discovery that the new product is the previously unknown, undetectable byproduct of a prior patented process.

If patent law and policy are to be transformed by a new, expansive doctrine of inherent anticipation – one that eviscerates the boundaries drawn by this Court in *Tilghman*